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Johnson Matthey Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD. and ACTELION CLINICAL RESEARCH, INC. Plaintiffs, - vs. - APOTEX INC., APOTEX CORP., ROXANE LABORATORIES, INC., ACTAVIS ELIZABETH LLC, and JOHNSON MATTHEY INC., Defendants.	Hon. Noel L. Hillman, U.S.D.J. Hon. Ann Marie Donio, U.S.M.J. Civil No. 1:12-cv-05743-NLH-AMD **JOHNSON MATTHEY INC.'s ANSWER, COUNTERCLAIM AND JURY DEMAND**

Intervenor-Defendant/Counterclaimant Johnson Matthey Inc.("JM"), a Pennsylvania corporation with its principal place of business at 435 Devon Park Drive, Suite 600, Wayne, Pennsylvania 19087, by way of answer to the Complaint of Plaintiffs Actelion Pharmaceuticals Ltd ("APL") and Actelion Clinical Research, Inc. ("ACR"; together with "APL," "Actelion" or "Plaintiffs"), says:

1. JM does not answer the allegations in Paragraph 1 since they characterize Plaintiffs' case and state legal conclusions. To the extent any answer may be required, JM denies the allegations in Paragraph 1, except to admit that Actelion purports to bring this case under 28 U.S.C. §§ 2201 and 2202.

2. JM admits, upon information and belief, that APL obtained approval from the Food and Drug Administration ("FDA") of a new drug application ("NDA") for Tracleer®, that Tracleer® may cause side effects, and that the FDA's approval of Tracleer® was subject to Actelion's implementation of a Risk Evaluation and Mitigation Strategy ("REMS"). JM denies the remaining allegations in Paragraph 2.

3. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and on that basis denies them.

4. JM does not answer the allegations in Paragraph 4 in that they state legal conclusions. To the extent that any answer is required, JM denies the allegations in Paragraph 4.

5. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 5 and on that basis denies them.

6. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 6 and on that basis denies them.

7. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 7 and on that basis denies them.

8. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 and on that basis denies them.

9. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 and on that basis denies them.

10. JM does not answer the allegations in Paragraph 10 since they state legal conclusions. To the extent any answer may be required, JM denies the allegations in Paragraph 10, except to admit that this Court has subject matter jurisdiction and further admits that Actelion purports to bring this case under 28 U.S.C. §§ 2201 and 2202.

11. JM does not answer the allegations in Paragraph 11 since they state legal conclusions. To the extent any answer may be required, JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 and on that basis denies them.

12. JM does not answer the allegations in Paragraph 12 since they state legal conclusions. To the extent any answer may be required, JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12 and on that basis denies them.

13. JM does not answer the allegations in Paragraph 13 since they state legal conclusions. To the extent any answer may be required, JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13 and on that basis denies them.

14. JM does not answer the allegations in Paragraph 14 since they state legal conclusions. To the extent any answer may be required, JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 and on that basis denies them.

15. JM admits that pulmonary arterial hypertension ("PAH") is a disorder. Upon information and belief, JM admits that Actelion Pharmaceuticals Ltd. submitted an NDA to FDA for PAH treatment. Upon information and belief, JM admits that Tracleer® is the proprietary name for Plaintiffs' PAH treatment. JM lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 15 and on that basis denies them.

16. JM does not answer the allegations in Paragraph 16 since they state legal conclusions. To the extent any answer may be required, JM denies the allegations in the first sentence of Paragraph 16 and lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 16, except to admit that the FDA Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations lists U.S. Pat. 5,292,740 under patent information for Tracleer®.

17. Upon information and belief, JM admits that Tracleer® may cause side effects. Upon information and belief, JM admits that FDA's approval of Tracleer® was conditioned on a REMS. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 17 and on that basis denies them.

18. JM denies the allegations in Paragraph 18 except it lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the final sentence of Paragraph 18 and on that basis denies them.

19. JM denies the allegations in Paragraph 19 except it lacks knowledge or information sufficient to form a belief as to the truth of the allegations in the final sentence of Paragraph 19 and on that basis denies them.

20. Upon information and belief, JM admits that Tracleer® may cause side effects and denies the remaining allegations in Paragraph 20.

21. JM admits that generic drug applicants submitting Abbreviated New Drug Applications ("ANDAs") generally must demonstrate bioequivalency to the innovator drug product. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 21 and on that basis denies them.

22. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 22 and on that basis denies them.

23. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23 and on that basis denies them.

24. JM denies the allegations in Paragraph 24 to the extent they suggest that Actelion has no duty or obligation to provide Zavesca® to JM, or that Actelion is otherwise entitled to any relief whatsoever. JM lacks sufficient information to admit or deny the remaining allegations in Paragraph 24, and on that basis, denies them.

25. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 25 and on that basis denies them.

26. JM denies the allegations of Paragraph 26 to the extent they suggest that Actelion has no duty or obligation to provide Zavesca® to JM, or that Actelion is otherwise entitled to any relief whatsoever. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 26 and on that basis denies them.

27. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 27 and on that basis denies them.

28. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 28 and on that basis denies them.

29. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29 and on that basis denies them.

30. JM denies the allegations in Paragraph 30 to the extent they suggest that Actelion has no duty or obligation to provide Zavesca® to JM, or that Actelion is otherwise entitled to any relief whatsoever. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 30 and on that basis denies them.

31. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 31 and on that basis denies them.

32. JM denies the allegations in Paragraph 32 to the extent they suggest that Actelion has no duty or obligation to provide Zavesca® to JM, or that Actelion is otherwise entitled to any relief whatsoever. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 32 and on that basis denies them.

33. JM does not answer the allegations in the first and second sentences of Paragraph 33 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations. JM does not answer the remaining allegations of Paragraph 33 since they purport to summarize provisions of the Food and Drug Amendments Act of 2007, 21 U.S.C. § 355-1 (the "REMS statute"), and the Tracleer® REMS, along with Actelion's duties thereunder. To the extent a response is required to these allegations, the statute cited and REMS

speak for themselves and are in their entirety the best evidence of their content. JM denies any allegations that are inconsistent with the plain language of the statute and Tracleer® REMS.

34. JM does not answer the allegations in Paragraph 34 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations.

35. JM does not answer the allegations in Paragraph 35 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations.

36. JM does not answer the allegations in Paragraph 36 since they purport to summarize provisions of the REMS statute. Insofar as these allegations state conclusions of law, no response is required. To the extent that the allegations may be deemed to state allegations of fact, the statute cited speaks for itself and is in its entirety the best evidence of its content. JM denies any allegations that are inconsistent with the plain language of the statute.

37. JM does not answer the allegations in Paragraph 37 since they purport to summarize and quote from provisions of the REMS statute and its legislative history. Insofar as these allegations state conclusions of law, no response is required. To the extent that the allegations may be deemed to state allegations of fact, the cited statute and its legislative history speak for themselves and are in their entirety the best evidence of their content. JM denies any allegations in Paragraph 37 that are inconsistent with the plain language of the statute and its legislative history.

38. JM does not answer the allegations in Paragraph 38 since they purport to summarize and quote from provisions of the Food and Drug Administration Safety and Innovation Act and its legislative history. Insofar as these allegations state conclusions of law, no response is required. To the extent that the allegations may be deemed to state allegations of fact, the cited statute and its legislative history speak for themselves and are in their entirety the

best evidence of their content. JM denies any allegations in Paragraph 38 that are inconsistent with the plain language of the statute and its legislative history.

39. JM does not answer the allegations in Paragraph 39 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations

40. JM does not answer the allegations in Paragraph 40 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations.

41. JM does not answer the allegations in the final sentence of Paragraph 41 since it contains legal conclusions to which no response is required. To the extent a response is required, JM denies these allegations. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 41 and on that basis denies them.

42. JM does not answer the allegations in Paragraph 42 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations.

43. JM does not answer the allegations in Paragraph 43 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations.

44. JM denies the allegations in the first sentence of Paragraph 44. JM does not answer the allegations in the final sentence of Paragraph 44 since it contains legal conclusions to which no response is required. To the extent a response is required, JM denies these allegations. JM lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 44 and on that basis denies them.

45. JM does not answer the allegations in Paragraph 45 since they state legal conclusions. To the extent any answer may be required, JM denies these allegations.

COUNT I
(Declaratory Relief)

46. JM repeats and incorporates its answers to Paragraphs 1 through 45 inclusive as if set forth fully herein.

47. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of first and second sentences of Paragraph 47 and on that basis denies them. The final sentence of Paragraph 47 contains legal conclusions to which no response is required. To the extent that a response is required, JM denies the allegations in the final sentence of Paragraph 47. JM denies the allegations in Paragraph 47 to the extent they suggest that Actelion has no duty or obligation to provide Zavesca® to JM, or that Actelion is otherwise entitled to any relief whatsoever.

48. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48 and on that basis denies them. JM denies the allegations in the second sentence of Paragraph 48 to the extent they suggest that Actelion has no duty or obligation to provide Zavesca® to JM, or that Actelion is otherwise entitled to any relief whatsoever.

49. JM lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 49 and on that basis denies them.

50. JM admits there is an actual controversy regarding Actelion's refusal to sell samples of Tracleer® and/or Zavesca® to generic manufacturers. JM does not answer the remaining allegations of Paragraph 50 since they contain legal conclusions to which no response is required. To the extent that a response is required, JM denies the remaining allegations of Paragraph 50.

51. JM denies the allegations in Paragraph 51.

PRAYER FOR RELIEF

JM further denies that Plaintiffs are entitled to the relief requested in the Complaint.

AFFIRMATIVE DEFENSES

JM hereby asserts the following affirmative defenses without assuming the burden of proof for issues where the burden would not ordinarily be upon the responding party.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Cause of Action)

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Equitable Estoppel)

As a result of their own acts and/or omissions, Plaintiffs are estopped, in whole or in part, from maintaining the cause of action asserted in, or obtaining the relief sought by, the Complaint.

THIRD AFFIRMATIVE DEFENSE
(Barred by FDA and Antitrust Laws)

Plaintiffs' claims are barred, in whole or in part, by FDA and antitrust laws.

FOURTH AFFIRMATIVE DEFENSE
(Additional Affirmative Defenses)

JM reserves all defenses at law or equity that may now exist or in the future be available on discovery and further factual investigation in this case.

WHEREFORE, JM demands judgment dismissing the Complaint with prejudice and with costs together with such other and further relief that this Court deems just and proper.

COUNTERCLAIM

Intervenor-Defendant/Counterclaimant JM, by way of counterclaim against Defendants on the Counterclaim Actelion Pharmaceuticals Ltd. ("APL") and Actelion Clinical Research ("ACR"; together with APL, "Actelion"), alleges and says:

NATURE OF THE LAWSUIT

1. This is a civil antitrust action under the Sherman Act, 15 U.S.C. §§ 1, *et seq.*, and the New Jersey Antitrust Act, N.J. Stat. § 56:9, seeking treble damages, a declaratory judgment, and injunctive relief against Actelion for unlawfully excluding generic manufacturers, including JM, from the U.S. market for FDA-approved miglustat drug products.

2. Miglustat drug product is a treatment for certain types of Gaucher's disease in adult patients. Actelion manufactures a miglustat drug product under the brand-name Zavesca®.

3. JM is a global supplier of pharmaceutical materials, including bulk active pharmaceutical ingredients ("API"). JM supplies bulk API to both branded and generic drug manufacturers. JM is actively developing a generic version of Zavesca®-brand miglustat and intends to submit an abbreviated new drug application ("ANDA") to the FDA for approval. JM has experience in developing pharmaceutical materials and has established procedures that it follows to fully comply with FDA requirements for conducting tests that require additional or special precautions. For example, JM developed and now manufactures controlled substances such as morphine and synthetic opiates, which are used to relieve or manage pain, and platinum-based API such as carboplatin and oxaliplatin, which are used in chemotherapy treatments.

4. The applicable regulatory regime requires an ANDA applicant to demonstrate that its proposed generic drug product is bioequivalent to the brand-name approved drug referenced in the ANDA. In order to demonstrate bioequivalence, JM must first obtain samples

of Zavesca® to perform the bioequivalence tests required for FDA approval. Upon receiving FDA approval, JM intends to market a generic version of Zavesca®.

5. Actelion controls access to Zavesca® samples and is blocking JM's entry into the market as a competitor by refusing to sell samples of Zavesca® to JM. JM has made multiple attempts to purchase Zavesca® from Actelion's distributors. Upon information and belief, Actelion has refused and continues to refuse to permit such distributors to sell Zavesca® samples directly to JM. In February 2013, JM sought and offered to purchase samples directly from Actelion at full retail price. On March 6, 2013, Actelion refused JM's request for samples.

6. Actelion's conduct violates antitrust law and is contrary to the Hatch-Waxman Act. The Hatch-Waxman Act was enacted to accelerate competition for approved drugs by creating an abbreviated approval pathway, which Actelion, through its conduct, unlawfully seeks to block. Actelion's refusal to sell Zavesca® to JM, coupled with its vertical and horizontal control over the miglustat market, prevents JM from conducting bioequivalence tests for approval of a generic miglustat drug product. As a result of Actelion's conduct, JM is suffering irreparable harm and injury to its business. In addition, Actelion's actions clearly have an anticompetitive effect on the market for miglustat products. Actelion's conduct harms consumers by preventing access to lower-priced generic miglustat drug products. Actelion is forcing all miglustat drug product purchasers and all third-party payors who ultimately bear the cost of miglustat drug product prescriptions to pay supra-competitive prices for Zavesca®.

THE PARTIES

7. Intervenor Defendant and Counterclaimant Johnson Matthey Inc. is a global supplier of pharmaceutical products, including bulk active pharmaceutical ingredients, and has its principal place of business at 435 Devon Park Drive, Suite 600, Wayne, Pennsylvania 19087.

8. Upon information and belief, Defendant on the Counterclaim APL is a pharmaceutical company with its principal place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

9. Upon information and belief, Defendant on the Counterclaim ACR is a Delaware corporation with its principal place of business at 1820 Chapel Avenue West, Suite 300, Cherry Hill, NJ, 08002. Upon information and belief, Actelion Clinical Research, Inc. is an affiliate of APL and manages the Zavesca® NDA and Zavesca® restricted distribution program in the United States as agent for APL.

10. Upon information and belief, Defendant Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada, M9L 1T9. Upon information and belief, Apotex Inc. makes and sells generic drug products.

11. Upon information and belief, Defendant Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida, 33326. Upon information and belief, Apotex Corp. makes and sells drug products.

12. Upon information and belief, Defendant Roxane is a Nevada corporation with its principal place of business at 1809 Wilson Road, Columbus, Ohio, 43228. Upon information and belief, Roxane makes and sells generic drugs.

13. Upon information and belief, Defendant Actavis Elizabeth LLC is a pharmaceutical company with its principal place of business at 200 Elmora Avenue, Elizabeth New Jersey, 07202. Upon information and belief, Actavis makes and sells generic drug products.

JURISDICTION AND VENUE

14. This Court has federal question jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a) because JM's claims arise under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26, to secure a declaratory judgment, recover damages, and secure injunctive relief against Actelion to prevent it from further violating Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and causing damage to JM as a result of those violations.

15. Because the state law claims arise out of the same facts, circumstances, and transactions as the federal law claims, this Court may exercise supplemental jurisdiction over those state law claims under 28 U.S.C. §§ 1331, 1337(a), and 1367.

16. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c).

17. This Court has personal jurisdiction over Defendants on the Counterclaim ACR and APL and they have purposefully availed themselves of the benefits of this judicial district by filing their Complaint here.

IMPACT ON INTERSTATE COMMERCE

18. Upon information and belief, Actelion is engaged in interstate commerce and in activities substantially affecting interstate commerce. Upon information and belief, Actelion's conduct alleged herein substantially affects interstate commerce. Upon information and belief, Actelion has subsidiaries with marketing and sales in more than twenty countries, and covers all key pharmaceutical markets worldwide. Upon information and belief, doctors across the county are able to prescribe Zavesca®, and Actelion sells Zavesca® to patients throughout the United States. By engaging in anticompetitive conduct to prevent generic entry, Actelion forces consumers in all states to pay supra-competitive prices for Zavesca®.

BACKGROUND

I. CONGRESS ENACTED THE HATCH-WAXMAN ACT TO PROVIDE AN EXPEDITED PROCESS FOR GENERIC DRUG ENTRY

19. The statutory framework at issue in this case includes the Food and Drug laws and the antitrust laws.

A. The Hatch-Waxman Act

20. In 1984, Congress created an expedited regulatory approval pathway for generic drugs in the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified at various sections of Titles 21 and 35 of the United States Code).

21. Among other provisions, the Hatch-Waxman Act created the ANDA process. By submitting an ANDA, generic manufacturers can avoid repeating time-intensive clinical trials if they demonstrate that the proposed generic drug product is bioequivalent to the brand-name listed drug. *See* 21 U.S.C. § 355(j)(2)(A). The abbreviated application process provides for an expedited regulatory approval pathway, thereby increasing competition in the pharmaceutical industry and helping to spur price competition.

22. The Hatch-Waxman Act also provided branded drug manufacturers with various exclusivity and patent term extension opportunities. *See, e.g.*, 35 U.S.C. § 156. The Hatch-Waxman Act was thus a compromise: brand-name manufacturers obtained longer exclusivity and patent protection in exchange for faster and cheaper generic entry once the exclusivity periods and patent protection ultimately expired.

23. Generic entry creates competition that not only brings down the prices of brand-name drugs, but results in the sale of less-expensive generic versions of the branded drugs, thereby providing significant savings to consumers and reducing overall health care costs.

B. The Food and Drug Administration Amendments Act of 2007

24. Section 505-1 of the Food, Drug, and Cosmetic Act ("FDCA") authorizes the FDA to require a risk evaluation and mitigation strategy ("REMS") for a drug if it determines that a REMS program is "necessary to ensure that the benefits of the drug outweigh the risks of the drug." The components of a REMS program can include requirements such as a medication guide and package insert, as well as potential restrictions on distribution of the drug. *See* 21 U.S.C. § 355-1(d)-(f).

25. The statute specifically provides for limited application of REMS programs to generic drugs. *See* 21 U.S.C. § 355-1(i)(1). For example, the statute states that drugs that are the subject of an ANDA are subject only to certain components of a REMS program – namely, a medication guide or patient package insert, and elements to assure safe use, if required for the listed drug. *See id.* at § 355-1(i)(1).

26. In addition, the statute prohibits approved drug manufacturers from using REMS programs to block or delay the approval of an ANDA: "No holder of an approved covered application shall use any element to assure safe use required by [FDA] under this subsection to block or delay approval of an [abbreviated new drug application or 505(b)(2) application] or to prevent application of such element . . . to a drug that is the subject of an abbreviated new drug application." 21 U.S.C § 355-1(f)(8).

27. The FDA does not require a REMS program for every approved drug. *See* 21 U.S.C. § 355-1(f). Even if not required to do so by the FDA, some manufacturers will voluntarily design, adopt, and implement a "restricted distribution" program for the drug product in order to prevent generic companies from acquiring samples. Upon information and belief, Zavesca® is not subject to an FDA-approved REMS program. Upon information and belief,

Actelion subjects Zavesca® capsules to a restricted distribution program, which Actelion independently designed and implemented without being instructed to do so by the FDA.

II. ACTELION CONTROLS ACCESS TO ZAVESCA® SAMPLES

28. The only patents listed in the FDA's "Orange Book" with respect to Zavesca® are United States Patents No. 5,472,969 ("the '969 Patent") and No. 5,525,616 ("the '616 Patent"). Upon information and belief, Actelion is the current assignee of the '969 and '616 Patents. According to the Orange Book, the '969 Patent will expire on May 13, 2013, and the '616 Patent will expire on June 11, 2013. Upon information and belief, the impending expiration of the Zavesca®-related patents creates a strong incentive for Actelion to engage in other tactics to preserve its monopoly on FDA-approved miglustat drug products.

29. In July 2003, the FDA approved Actelion's new drug application ("NDA") to market Zavesca®-branded miglustat capsules. Miglustat capsules are used to treat adult patients with certain types of Gaucher's disease for whom alternative treatments, such as enzyme replacement therapy, is inappropriate or otherwise unavailable.

30. Upon information and belief, Zavesca® is the only FDA-approved miglustat pharmaceutical. Upon information and belief, there are no generic alternatives to Zavesca®.

31. Upon information and belief, the price that Actelion charges for Zavesca® is well in excess of the cost of production, as is the case for most branded drugs that do not face generic competition.

32. Upon information and belief, Actelion markets and sells FDA-approved pharmaceutical products containing miglustat as the active ingredient in the United States.

33. Upon information and belief, Actelion has adopted and implemented a "restricted distribution" program to control the distribution of Zavesca® capsules. Upon

information and belief, Actelion's Zavesca® distributors have not and cannot supply Zavesca® without Actelion's approval. In so doing, Actelion can block and/or delay a prospective generic applicant from obtaining a sufficient quantity of the drug product to conduct required bioequivalence testing.

34. Upon information and belief, the FDA has not approved any REMS for Zavesca®. Upon information and belief, the only restricted distribution system for Zavesca® is one instigated, designed, and implemented by Actelion.

III. JM's EFFORTS TO OBTAIN TESTING SAMPLES OF MIGLUSTAT

35. JM has, at all relevant times, intended to and currently intends to enter the market for miglustat drug products. To that end, JM has taken actual and substantial affirmative steps toward entering the miglustat market. JM is actively developing a generic miglustat product and has made a considerable investment thus far in developing and manufacturing the API, miglustat, which is one of the most expensive and time-intensive components of developing a generic drug product. JM's progress, however, was prematurely halted by Actelion's refusal to provide access to Zavesca® samples. Indeed, JM has been attempting (unsuccessfully) to obtain Zavesca® samples for over twenty months. In addition to contacting known distributors, JM wrote to the FDA seeking its assistance in directing Actelion to issue limited quantities of Zavesca® to JM for the purpose of performing bioequivalence tests. The FDA, however, declined to assist, explaining that it could not force Actelion to provide samples, in part because Actelion's restricted distribution plan was not an FDA-mandated REMS. JM has therefore exhausted its options for obtaining Zavesca® samples.

36. On February 18, 2013, JM made a written request to Actelion to purchase a limited number of Zavesca® capsules for fair market value plus shipping, handling, and other

reasonable costs. JM stated that the Zavesca® capsules would be used to support bioequivalence studies and to maintain the legally-required amount of reserve samples required for such studies. *See* 21 C.F.R. §§ 320.38, 320.63. In the written request, JM assured Actelion that it had established procedures in place that fully complied with FDA requirements for testing Zavesca®, and that these procedures were appropriate substitutes for the controls present in the Zavesca® restricted access program.

37. In a March 6, 2013 letter to JM, Actelion refused JM's request to purchase Zavesca® at full retail price, asserting that Actelion has "a right to choose with whom it does business and to whom it sells its products," and that the "FDA-required restricted distribution plan . . . would not allow distribution" to JM.

38. In the same letter, Actelion did not provide a basis for its statement that the FDA required the asserted restricted distribution plan. Actelion did not specify nor offer to discuss what specific safeguards JM would have to meet in order to obtain testing samples from Actelion.

IV. ACTELION'S EXCLUSIONARY AND MONOPOLISTIC CONDUCT

39. The relevant product market in this case is the market for FDA-approved miglustat drug products.

40. The relevant geographic market is the United States of America.

41. Actelion, through sales of Zavesca®, controls one hundred percent of the market for sales of FDA-approved miglustat drug products in the United States. Upon information and belief, Zavesca® is the only branded miglustat drug that is FDA-approved, and the FDA approval process for NDAs serves as a significant barrier to new drug entry into this

market. Upon information and belief, there are no other FDA-approved drugs containing miglustat as the active ingredient, and there are no reasonably interchangeable substitutes.

42. Actelion exercises monopoly power in the relevant market. There are no generic competitors to Actelion's Zavesca®. The only feasible way for a generic competitor to enter this market requires obtaining a sample of Zavesca®. However, Actelion has complete control over the distribution of Zavesca® and, by extension, control over the ability of competitors to enter the relevant market in a way that is economically feasible.

43. Actelion's refusal to sell samples to generic drug developers has had anticompetitive effects in the relevant market by blocking, delaying, and eliminating competition in the manufacture and sale of miglustat drug products. Actelion's refusal to sell samples of Zavesca® to JM and Actelion's restrictions on distribution to prevent generic competition in the miglustat market are not reasonably necessary to achieve any legitimate ends given JM's established procedures for complying with FDA protocols.

44. Actelion's conduct has forced consumers who need miglustat to purchase Zavesca® at artificially high and noncompetitive price levels and denied those consumers the availability of a lower cost generic miglustat product. Until Actelion permits generic competitors access to the necessary means to enter the market (*i.e.*, access to Zavesca® for bioequivalence testing), consumers who need miglustat will be forced to purchase Zavesca® at artificially high and noncompetitive price levels, and will be denied the availability of a lower cost generic miglustat product.

45. But for Actelion's wrongful conduct in blocking JM's access, JM would have been able to promptly conduct and complete studies showing the bioequivalence of JM's proposed generic formulation with Zavesca® and then promptly file an acceptable ANDA with

the FDA. Actelion's wrongful conduct has directly caused significant delays in JM's preparation and filing of its ANDA for a miglustat drug product. But for Actelion's self-imposed restricted distribution program for Zavesca®, JM could have purchased Zavesca® samples months ago and thus would have been months further along in the bioequivalency testing and ANDA preparation process. In fact, JM has been trying to obtain samples unsuccessfully for over twenty months. After JM obtains samples, JM will conduct the necessary bioequivalence studies and promptly file its ANDA thereafter. Following FDA approval, JM intends to bring its generic miglustat product to market. Given that the patents that allegedly cover Zavesca® are set to expire this summer, Actelion has already succeeded in unlawfully extending its monopoly for miglustat by blocking generic ANDA submissions and delaying generic entry into the market. Actelion's anticompetitive conduct has therefore specifically harmed JM by blocking and delaying JM's entry into the generic miglustat market.

COUNT I
(Sherman Act, § 2 – Monopolization, Attempted Monopolization, and Conspiracy to Monopolize)

46. JM repeats and realleges the allegations in Paragraphs 1 to 45 inclusive of the Counterclaim as if set forth fully herein.

47. A nationwide market exists within the United States for the sale of FDA-approved miglustat drug products. Actelion has monopoly power in this market as demonstrated by, inter alia, its present monopoly on the sale of miglustat drug products, the high barriers to entry into the market (including those imposed by Actelion), its substantial share of the relevant market(s), and/or the comparative lack of substitutes. There is also a dangerous probability that Actelion will succeed in maintaining its monopoly by means of its unlawful conduct.

48. Actelion's monopoly power does not result from Actelion's patents. Actelion will continue to control distribution of Zavesca® when the '969 and '616 Patents expire or are found invalid or unenforceable because the distribution restrictions imposed by Actelion as part of its restricted distribution program make Actelion the only source from which generic developers can obtain samples for the purpose of demonstrating bioequivalency. The status of the '969 and '616 Patents and Actelion's rights as the assignee of these patents are irrelevant, except insofar as the patents' imminent expiration provides Actelion with an incentive to engage in anticompetitive tactics to preserve its monopoly.

49. By refusing to provide samples, Actelion is able to use its monopoly power to prevent the entry of any generic competition because it has made it impossible for generic manufacturers of miglustat to enter the market for FDA-approved miglustat drug products with a bioequivalent generic miglustat product, and economically infeasible to do so through the NDA route.

50. As a result of Actelion's monopolization and attempted monopolization of the market for FDA-approved miglustat drug products, Actelion has suppressed generic entry and therefore reduced output and increased the prices paid by consumers.

51. Actelion has no current competitors in the miglustat market. Actelion maintains monopoly power and conspires to maintain its monopoly by creating restricted distribution systems with distributors that unlawfully block or delay generic entry. *See* 21 U.S.C § 355-1(f)(8) ("No holder of an approved covered application shall use any element to assure safe use required by [the FDA] under this subsection to block or delay approval of an [ANDA] . . . .").

52. Through the actions described above, Actelion knowingly and intentionally engaged in an anticompetitive scheme designed to block or delay approval of a bioequivalent generic version of Zavesca® and thus to unlawfully maintain Actelion's monopoly power.

53. Actelion's exclusionary conduct constitutes unlawful monopolization, attempted monopolization, and conspiracy to monopolize in the relevant market in violation of Section 2 of the Sherman Act. That violation and its anticompetitive effects are continuing and will continue unless injunctive relief is granted.

54. Actelion's suggestion that samples of its branded drug products are "unnecessary" because JM and other potential generic entrants "can file an NDA [in lieu of an ANDA]" (Complaint ¶ 44) is simply not feasible and flatly undermines congressional intent. The Hatch-Waxman Act specifically provided for an abbreviated process for generic drugs in order to make it economically feasible for generics to enter the market and provide consumers with less expensive products. Withholding samples in order to force generic competitors to instead go through the NDA process makes it prohibitively expensive and slow for those competitors to enter. If Actelion's conduct continues, Actelion will be able to extend its monopoly indefinitely – the very outcome that Congress enacted the Hatch-Waxman Act to prevent.

55. Moreover, there are no legitimate business reasons for Actelion's refusal to grant generics access to Zavesca® samples. The FDA has not approved a REMS program for Zavesca®. Actelion designed and implemented a restricted distribution system that would prevent generic competitors from accessing samples and entering the miglustat market. JM has established protocols that include safeguards to ensure restricted access and patient safety, as required by the FDA. The fact that Actelion implemented a restricted distribution system is not a

legitimate basis for withholding the samples. Actelion's pretextual refusal to provide the samples prevents generic entry and maintains its monopoly power.

56. Actelion's unlawful monopolization, attempted monopolization, and conspiracy to monopolize as set forth above has had the following effects:

a. Competition in the manufacture and sale of miglustat is restrained, suppressed and eliminated;

b. Purchasers of Zavesca® are and will be deprived of the benefits of free and open competition in the purchase of Zavesca®, and the availability of a lower cost generic miglustat product has been and will be denied, prevented and/or delayed; and

c. Actelion has sold and will continue to sell Zavesca® at artificially high and noncompetitive price levels.

57. JM has been injured in its business or property by Actelion's unlawful conduct alleged herein. Specifically, Actelion's unlawful monopolization has precluded or substantially delayed the entry of JM's generic miglustat drug product in the United States. As a result, JM has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities as long as Actelion's unlawful conduct is not enjoined by this Court. Such unlawful conduct has also and will in the future increase JM's cost of entering into and supplying the market for miglustat.

58. JM has suffered damages in an amount to be proven at trial.

COUNT II

(Sherman Act, § 2 – Monopolization, Attempted Monopolization, and Conspiracy to Monopolize by Denial of an Essential Facility or Resource Necessary to Compete)

59. JM repeats and realleges the allegations in Paragraphs 1 to 58 inclusive of the Counterclaim as if set forth fully herein.

60. Actelion's conduct also violates Section 2 because it has refused to provide JM with access to an essential facility. FDA-approved Zavesca® is an essential resource for bioequivalence testing required to obtain FDA approval of a generic miglustat product. As a result, Actelion's distribution of Zavesca® is an essential facility for the production of generic miglustat.

61. There are four elements necessary to establish liability under the essential facilities doctrine: (1) control of the essential facility by a monopolist; (2) competitors' inability practically or reasonably to duplicate the essential facility; (3) the denial of the use of the facility to a competitor; (4) the feasibility of providing the facility.

62. First, Actelion has complete control over the samples, which are essential to compete with Actelion. Second, JM cannot practicably or reasonably duplicate the essential facility. As noted above, the NDA process is not an economically feasible path for generic entry. Third, Actelion has denied JM, a competitor, access to Zavesca® for the purposes of establishing bioequivalence of a generic product. Finally, it is entirely feasible for Actelion to provide JM with the samples; JM is willing to pay retail prices and cover any shipping or other related costs.

63. Moreover, there are no legitimate business reasons for Actelion's refusal to deal. The FDA has not approved a REMS program for Zavesca®. Actelion designed and implemented a restricted distribution system that would prevent generic competitors from accessing samples and entering the miglustat market. JM has established protocols that include

safeguards to ensure restricted access and patient safety, as required by the FDA. The fact that Actelion implemented a restricted distribution system is not a legitimate basis for withholding the samples. Actelion's pretextual refusal to provide the samples prevents generic entry and maintains its monopoly power.

64. Actelion's unlawful monopolization, attempted monopolization, and conspiracy to monopolize as set forth above has had the following effects:

a. Competition in the manufacture and sale of miglustat is restrained, suppressed and eliminated;

b. Purchasers of Zavesca® are and will be deprived of the benefits of free and open competition in the purchase of Zavesca®, and the availability of a lower cost generic miglustat product has been and will be denied, prevented and/or delayed; and

c. Actelion has sold and will continue to sell Zavesca® at artificially high and noncompetitive price levels.

65. JM has been injured in its business or property by Actelion's unlawful conduct alleged herein. Specifically, Actelion's unlawful refusal to provide JM access to an essential facility has precluded or substantially delayed the entry of JM's generic miglustat drug product in the United States. As a result, JM has suffered and will continue to suffer injury to its business and property, including lost profits, out-of-pocket costs, and lost business opportunities as long as Actelion's unlawful conduct is not enjoined by this Court. Such unlawful conduct has also and will in the future increase JM's cost of entering into and supplying the market for miglustat.

66. JM has suffered damages in an amount to be proven at trial.

COUNT III
(Sherman Act, § 1– Conspiring or Agreeing to Restrain Trade)

67. JM repeats and realleges the allegations in Paragraphs 1 to 66 inclusive of the Counterclaim as if set forth fully herein.

68. Actelion has violated Section 1 of the Sherman Act, 15 U.S.C. § 1, by conspiring, combining, and/or agreeing to restrain trade in the market for FDA-approved miglustat drug products.

69. Through the foregoing acts, Actelion has acted pursuant to a contract, combination, and/or conspiracy to unreasonably restrain trade in the market for FDA-approved miglustat drug products.

70. Upon information and belief, Actelion has agreed with at least its distributor CuraScript, and other participants, not to supply miglustat to any entity without Actelion's approval. By restricting downstream distribution of the drugs only to entities Actelion approves, Actelion is able to effectively foreclose all potential competitors from access to an essential input in the generic drug development process, and thus unlawfully "block or delay approval," 21 U.S.C. § 355-1(f)(8), of a competing generic version of Zavesca®, using its restricted distribution program as a pretext.

71. Each agreement with distributors to prohibit generic manufacturers access to Zavesca® samples substantially, unreasonably, and unduly restrains trade in the relevant market, and harms JM thereby.

72. There is no legitimate, procompetitive business justification for Actelion's agreements with distributors to prohibit generic manufacturers from accessing Zavesca® samples. Even if there were a business justification, upon information and belief, the agreements are more restrictive than necessary to achieve such purpose.

73. The foregoing acts and practices have harmed consumers and competition.

74. Actelion's unlawful restraint of trade as set forth above has had the following effects:

a. Competition in the manufacture and sale of miglustat is restrained, suppressed and eliminated;

b. Purchasers of Zavesca® are and will be deprived of the benefits of free and open competition in the purchase of Zavesca®, and the availability of a lower cost generic miglustat product has been and will be denied, prevented and/or delayed; and

c. Actelion has sold and will continue to sell Zavesca® at artificially high and noncompetitive price levels.

75. JM has been injured in its business or property by Actelion's unlawful conduct alleged herein. Specifically, Actelion's unlawful agreements have precluded or substantially delayed the entry of JM's generic product in the United States. As a result, JM has suffered and will continue to suffer injure to its business and property, including lost sales and profits, out-of-pocket costs, and lost business opportunities, as long as Actelion's unlawful conduct is not enjoined by this Court. Such unlawful conduct has also and will in the future increase JM's cost of entering into and supplying the market for miglustat.

76. JM has suffered damages in an amount to be proven at trial.

COUNT IV
(New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4 – Monopolization)

77. JM repeats and realleges the allegations in Paragraph 1 to 76 inclusive of the Counterclaim as if set forth fully herein.

78. Actelion's anticompetitive conduct constitutes monopolization and attempted monopolization in violation of the New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4(a).

79. Actelion has improperly extended and maintained its monopoly power in the relevant market within New Jersey as set forth above by unreasonably suppressing generic entry, prolonging Actelion's monopoly, and thereby reducing output and increasing prices paid by consumers.

80. Actelion's unlawful monopoly has had the anticompetitive effects alleged above.

81. As a result of Actelion's unlawful conduct, JM has been injured in its business by delaying JM's entry into the relevant market within New Jersey.

82. JM has suffered damages in an amount to be proven at trial.

COUNT V

(New Jersey Antitrust Act, N.J. Stat. Ann. § 56:9-4 – Denial of an Essential Facility)

83. JM repeats and realleges the allegations in Paragraphs 1 to 82 inclusive of the Counterclaim as if set forth fully herein.

84. Actelion's conduct as set forth above also constitutes monopolization and attempted monopolization in violation of N.J. Stat. Ann. § 56:9-4(a), because it has denied JM the use of an essential facility necessary to compete in the relevant market within New Jersey. FDA-approved Zavesca® is an essential resource for the bioequivalence testing required to obtain FDA approval of a generic miglustat product. As a result, Actelion's refusal to sell Zavesca® to JM is an unlawful denial of an essential facility necessary for any competitors to enter the relevant market within New Jersey.

85. Actelion's unlawful monopoly has had the anticompetitive effects alleged above.

86. As a result of Actelion's unlawful conduct, JM has been injured in its business by delaying JM's entry into the relevant market within New Jersey.

87. JM has suffered damages in an amount to be proven at trial.

COUNT VI
(Tortious Interference)

88. JM repeats and realleges the allegations in Paragraphs 1 to 87 inclusive of the Counterclaim as if set forth fully herein.

89. Actelion's conduct gives rise to common law liability for tortious interference with prospective business relations and economic advantage.

90. JM has reasonable expectations of economic advantage resulting from its prospective contractual or economic relationships with third parties upon the approval of its generic miglustat product and entry into the relevant market.

91. Actelion intentionally refuses to sell samples of Zavesca® to JM with the primary purpose of suppressing generic entry and preventing JM's resulting prospective economic relationships and advantages. Actelion's conduct is malicious, anticompetitive and an unlawful use of restricted distribution systems to prevent generic entry. Actelion's intentional infliction of harm is without justification or excuse.

92. If Actelion had not interfered, JM would not be delayed in entering the relevant market and would receive the anticipated benefit of sales and profits from generic entry.

93. Actelion's interference has directly and proximately caused injury to JM's business, as it has delayed JM's entry in the relevant market. If Actelion's conduct continues unrestrained, it will not only delay, but entirely prevent JM's entry in the relevant market. JM is entitled to the damages it suffered as a result of Actelion's tortious interference in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, JM demands judgment on its Counterclaim that:

(i) Actelion's unlawful conduct be declared, adjudicated and decreed a violation of the Sherman Act, 15 U.S.C. §§ 1 and 2, the New Jersey Antitrust Act, N.J. Stat. Ann. § 59:9-4, and New Jersey common law of tortious interference;

(ii) JM be granted injunctive relief enjoining and restraining Actelion from limiting distribution of Zavesca® samples to JM through use of its "restricted distribution" programs or otherwise;

(iii) JM recover compensatory damages, including treble damages pursuant to 15 U.S.C. § 15 and N.J. Stat. Ann. § 56:9-12;

(iv) JM be awarded expenses and costs of suit, including reasonable attorneys' fees, to the extent provided by law; and

(v) JM be awarded such additional relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), JM demands a trial by jury on all issues so triable herein.

LOCAL RULE 11.2 CERTIFICATION

We hereby certify that the matters in controversy in the above-captioned action are not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Date: April 5, 2013

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Johnson Matthey Inc.

By: s/ Andrew Muscato
Andrew Muscato